

Remarks:

Claims 34-66 are pending in this application. Applicant has amended claims 34-37, 41, 42, 44-48, and 50-66 to clarify the present invention. Applicant respectfully requests favorable reconsideration of this application.

Applicant has amended claims 34, 52, and 65 to recite that the P-wave excludes atrial extrasystoles. This is described in the specification at page 4, lines 24-26, and page 7, lines 34-36, among other passages. Additionally, Applicant has amended claims 34, 52, and 65 to recite that the detected P-wave is compared to a reference P-wave of the ECG signal. The specification describes this at page 4, lines 4-9, and 14-16, among other passages.

A benefit of the present invention as recited in the pending claims includes analysis of dynamic changes of the configuration of normal P-waves, which might otherwise be considered uninteresting. Typically, in the field of electrocardiography, the common approach is to detect "abnormalities" in P-waves. The idea that analyzing normal P-waves may be valuable has never been mentioned nor even remotely suggested in the field.

The Examiner rejected claims 37, 50, 55, and 63 under 35 U.S.C. § 112, second paragraph, as indefinite.

The beat between two R-peaks is the time between two successive R peaks. The concept of a "beat" is unambiguous in this context, because it is self-evident in the field of cardiology

that the time between two R peaks is called "a beat" (a heart beat), and it cannot be an arbitrary shorter period between two R peaks. The term "beat" is also explained in the specification at page 7, lines 22-26.

Claims 50 and 63 have been amended to clarify the "data storage unit". The specification at page 7, lines 2-13, describes the data storage unit as a data storage unit registering electrical signals of the heart.

In view of the above, claims 37, 50, 55, and 63 comply with 35 U.S.C. § 112, second paragraph, and Applicant respectfully requests withdrawal of this rejection.

The Examiner rejected claims 34, 38-43, 49, 50-52, and 56-65 under 35 U.S.C. § 102(b) as being anticipated by WO 01/76461 to Groenewegen et al. The Examiner rejected claims 35-37, 44-48, 53-55, 58, and 66 under 35 U.S.C. § 103(a) as being unpatentable over Groenewegen et al. in view of U.S. published patent application 2002/0082510 to Toole et al.

Groenewegen et al. does not disclose the present invention as recited in claims 34, 52, or 65 since, among other things, Groenewegen et al. does not disclose calculating parameter values of P-waves excluding atrial extrasystoles. Normal P-waves originate in the sinus node of the heart. Rather, Groenewegen et al. discloses concentrating solely on detection and classification of various arrhythmias, or abnormal heart beats. Accordingly, Groenewegen et al. disclose examining the P-wave occurring during arrhythmia. Groenewegen et al. describes this at page 12, second paragraph, for example.

Extrasystoles are defined on the website <http://heart.health.ivillage.com/> as follows:

Extrasystoles: Heart beats caused by electrical pacing signals that do not originate in the sinus node (the heart's natural pacemaker). They may originate in the atria (PACs), ventricles (PVSs) or the AV junction (PJs).

Alternate Terms:

Ectopics

Premature Beats

Premature Contractions

Additionally, at page 5, in the initial section of the second paragraph Groenewegen et al. discusses attempts to correlate changes in P-wave morphology and polarity with various locations of ectopic activity. The words "ectopic activity" exemplify the whole idea of Groenewegen et al., namely to examine atrial extrasystoles which are not normal native P-waves originating in the heart's sinus node. For example, Figures 7A and 7B in Groenewegen et al. help to understand the basic idea in an illustrative manner: the anatomical pictures show how different mean P-wave integral maps correlate with the pacing origin in the left atrium.

In fact, differences between the present invention as recited in claims 34, 52, and 65 and Groenewegen et al. is clearly visible simply from the title of Groenewegen et al., which reads: "Database of body surface ECG P-wave integral maps for localization of left-sided atrial arrhythmias" (emphasis added). The purpose of the present invention as recited in claims 34, 52, and 65 is not to detect and localize atrial arrhythmias. Figure 1 which is published together with the abstract in Groenewegen et al. also presents a clear difference from the present invention, particularly in comparison to the method as recited in claim 34.

The Examiner cites passages of Groenewegen et al., including page 6, lines 18–19 and 23–25, in discussing ECG P-wave data maps, which are only for localization of left atrial arrhythmias, not for detecting dynamic changes of the normal p-wave of an ECG signal during a defined time period, as recited in claims 34, 52, and 65. Also, other passages cited by the Examiner only describe creating databases for finding abnormal situations in later ECG recordings, because various arrhythmias can be detected and classified on the basis of data previously collected.

One aim of the present invention as recited in claims 34, 52, and 65 is to detect dynamic changes of a normal P-wave of an ECG signal that has been obtained and processed to a suitable form for analysis. An important aspect of the claimed invention is detecting and analyzing changes in P-wave obtained from the ECG signal as compared to a P-wave obtained during a recording period. The comparison may be made internally based on an ECG recording from one person. This is described in the specification, for example, at page 4, lines 18-19; page 4, lines 31-32; and page 10, lines 31-34. This is also apparent from the other passages of the specification and specific examples.

Thus, the general idea of Groenewegen et al. is to compare abnormal P-waves with a reference to classify them and not to continuously monitor dynamic changes of a normal P-wave, that is, a P-wave originating in the sinus node. This difference between the claimed invention and Groenewegen et al. is emphasized by the fact that this classification is mentioned in the present application only as an additional and optional feature on page 4, lines 24-26, of the

specification. Furthermore, at page 7, lines 26-36, the separation of the atrial extrasystoles from the analysis is described. Thus, in the present invention as recited in claims 34, 52, and 65, "P-wave" means a wave from the sinus node and different from atrial extrasystoles, because they were clearly contrasted in these sections of the description.

With respect to claims 38, 39, 56 and 57, a significant difference between the present invention and Groenewegen et al. is that the templates disclosed by Groenewegen et al. are issued from a databank created from abnormal P-waves occurring in other persons, whereas according to the present invention as recited in claims 34, 52, and 65, the template is obtained from the same individual during the same recording, in the beginning thereof through averaging.

Regarding claims 41 and 59, Groenewegen et al. does not disclose the methodology recited in these claims. Along these lines, a 2 ms interval in Groenewegen et al. means the sampling interval, a time period during which no data is gathered. On the other hand, according to the present invention as recited in claims 41 and 59, the interval has a totally different function, which is the time period during which the p-waves are collected for averaging, thus an interval of considerably longer duration.

In view of the above, Groenewegen et al. does not disclose all elements of the present invention as recited in claims 34, 38-43, 49, 50-52, and 56-65. Since Groenewegen et al. does not disclose all elements of the present invention as recited in claims 34, 38-43, 49, 50-52, and 56-65, the present invention, as recited in claims 34, 38-43, 49, 50-52, and 56-65, is not properly rejected under 35 U.S.C. § 102(b). For an anticipation rejection under 35 U.S.C. § 102(b) no difference may

exist between the claimed invention and the reference disclosure. *See Scripps Clinic and Research Foundation v. Genentech, Inc.*, 18 U.S.P.Q. 841 (C.A.F.C. 1984).

Along these lines, anticipation requires the disclosure, in a cited reference, of each and every recitation, as set forth in the claims. *See Hodosh v. Block Drug Co.*, 229 U.S.P.Q. 182 (Fed. Cir. 1986); *Titanium Metals Corp. v. Banner*, 227 U.S.P.Q. 773 (Fed. Cir. 1985); *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 1 U.S.P.Q.2d 1081 (Fed. Cir. 1986); and *Akzo N.V. v. U.S. International Trade Commissioner*, 1 U.S.P.Q.2d 1081 (Fed. Cir. 1986).

The combination of Groenewegen et al. and Toole does not suggest the present invention as recited in claims 35–37, 44–48, 53–55, 58, and 66 since, among other things, Toole does not overcome the above-described deficiencies of Groenewegen et al. For example, neither Groenewegen et al. nor Toole suggests calculating parameter values of at least one wave of an ECG signal, wherein the at least one wave is a P-wave excluding atrial extrasystoles. Additionally, neither Groenewegen et al. nor Toole suggests comparing data obtained from one individual during one recording.

Toole suggests creating a model for a normal heart vector by measurements of healthy volunteers. An individual's heart vector is then compared to this "normalized" heart vector. On the other hand, a kind of model representing a specific condition of heart disease can be created by measurements from a group of persons having this condition, and again, the heart vector of an individual can be compared to this model, as described at page 1, paragraph 0006). In both cases, the measurement data from the individual is compared with a general model, not with the

measurement data from the same individual, let alone the measurement data during one single recording. Toole again describes this at page 3, paragraph 0055.

Claims 35, 53 and 66 recite the novel idea of monitoring dynamic changes of a PQ segment as a further option. No known reference prior to the date of present invention suggests analyzing dynamic changes of a PQ segment in course of time in one individual during one recording. Toole only refers to PQ sector at page 5, claim 7, with respect to a sample of a specified grouping of persons (see p. 4, claim 1 of Toole). Again, this is a totally different approach as compared to the claimed invention.

In fact, what Groenewegen et al. and Toole have in common is that both references suggest comparing measurement data obtained from an individual with external data, which may be data from a data bank or a model. Both references very clearly teach away from the claimed invention, which compares data obtained from one individual during one recording. Also, both Groenewegen et al. and Toole are silent about dynamic changes of the P-wave.

In view of the above, the references relied upon in the office action, whether considered alone or in combination, do not disclose or suggest patentable features of the present invention. Therefore, the references relied upon in the office action, whether considered alone or in combination, do not anticipate the present invention or make the present invention obvious. Accordingly, Applicant respectfully requests withdrawal of the rejections based upon the cited references.

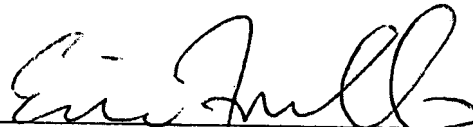
In conclusion, Applicant respectfully requests favorable reconsideration of this case and early issuance of the Notice of Allowance.

If an interview would advance the prosecution of this case, Applicant urges the Examiner to contact the undersigned at the telephone number listed below.

The undersigned authorizes the Commissioner to charge fee insufficiency and credit overpayment associated with this communication to Deposit Account No. 22-0261.

Respectfully submitted,

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